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RUEHZN/ENVIRONMENT SCIENCE AND TECHNOLOGY COLLECTIVE

UNCLAS SECTION 01 OF 06 NEW DELHI 002166

STATE FOR OES/PCI, OES/STC, OES/SAT, OES/EGC, AND SCA/INS
STATE FOR STAS
STATE PASS TO NSF FOR INTERNATIONAL PROGRAMS
HHS PASS TO NIH
STATE PASS TO USAID
STATE FOR SCA, OES (STAS FEDOROFF), OES/PCI STEWART; OES/IHB MURPHY
PASS TO HHS/OGHA (STEIGER/ABDOO/VALDEZ), CDC (BLOUNT/FARRELL),
NIH/FIC (GLASS/MAMPILLY/HANDLEY), FDA (LUMPKIN/WELSCH, GENEVA FOR
HOFMAN)
PASS TO MAS/DAS/JESTRADA
PASS TO MAC/DAS/HVINEYARD

SENSITIVE
SIPDIS

E.O. 12958: N/A
TAGS: [TBIO](#) [SENV](#) [AMED](#) [CASC](#) [KSQA](#) [ECON](#) [ETRD](#) [BEXP](#) [EINV](#) [PGOV](#)
SUBJECT: NEW DELHI BI-WEEKLY ESTH REPORT

REF: NEW DELHI 1086

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¶1. (U) SUMMARY: This edition of the New Delhi ESTH biweekly includes an S&T section update on the new Indian Institutes of Technology and a new Indian public-private partnership to assist small and medium scale entrepreneurs and the postponement of the launch of the Indian lunar mission "Chandrayan-I". The environment section reports on the need to design and market better cooking stoves due to the environmental risks of respiratory diseases. The health section includes information about the upcoming FDA Good Clinical Practices (GCP) workshop, an update on the meeting with the Drug Controller General of India on policy and regulatory affairs, the status of the creation of the Central Drug Authority, and HHS India Health Office support to visiting Medical Device and Pharmaceutical Policy Mission of the U.S. - India High-Technology Cooperation Group and upcoming health related workshops. The health report also includes a HHS/CDC Lab Assessment of National Reference Laboratories and a media report of suspected Hantavirus in India, in addition to an Avian Influenza and Polio Update and news on the Food Safety and Standards Authority new CEO appointment. END SUMMARY.

New Indian Institute of Technologies start functioning

¶2. (U) The Ministry of Human Resource Development (MHRD) announced the opening of eight new Indian Institutes of Technologies (IITs) this year in the States of Bihar, Andhra Pradesh, Himachal Pradesh, Gujarat, Madhya Pradesh, Orissa, Punjab, and Rajasthan, with an allocation of USD 25 million each for their establishment. The older IITs are expected to mentor the new IITs to help them establish themselves. All of them except the one at Madhya Pradesh are expected to start functioning from temporary campuses by the end

of this month. Minister of State for Higher Education Ms Purandeswari inaugurated the first of the new IITs, IIT Rajasthan on August 2, 2008, which started functioning from its mentor institute's campus at IIT Kanpur. MHRD Minister Arjun Singh will inaugurate IIT Bihar on August 7, 2008. It will start functioning from a temporary campus in Patna. All the IITs are expected to have their own permanent campus in 2 years time. The biggest challenge for these IITs will be finding capable faculty. Due to capacity addition on account of the MHRD's new reservation policy, they are cumulatively expected to need about 3000 faculty in the next couple of years. To at least temporarily overcome this problem, the MHRD and the IITs together seem to be planning to develop a special package to rehire IIT faculty who retire at the age of 65 and also scientists who retire at age of 60 from Council for Scientific and Industrial Research (CSIR) labs (a cluster of 39 national laboratories). Finding the remaining faculty will be a very daunting task.

Industrial body and Government come together to help Micro, Small, and Medium Entrepreneurs (MSME) innovate

¶3. (U) The Confederation of Indian Industries (CII), an industry led and managed NGO, and the Indian Department of Scientific and Industrial Research (DSIR), which manages 39 national laboratories, have joined hands to help Indian MSMEs. The public-private partnership is called the Technology Export Development Organization (TEDO) and it hopes to enhance the technological competitiveness of MSMEs. This year TEDO has selected 150 companies spanning 6 different sectors to help to innovate and add value to their products and then export the same through participation in international exhibitions in the target country. The sectors are automobile components, agro food processing, dies and molding,

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casting and forging, process plant and machinery, and Information Technology enabled Engineering Services. They have involved about 33 consultants with diverse domain expertise to help these MSMEs. As reported earlier the GOI has also set up provision for free patent filing by MSMEs (Reftel).

Indian Moon Mission "Chandrayan-I" Postponed

¶4. (SBU) Indian's unmanned moon mission "Chandrayan-I" which was planned for launch by mid September has been postponed. According to press reports, Indian Space Research Organization (ISRO) Chairman G Madhavan Nair has said that the new date would probably be around 15 October 2008. Dr. Madhavan Nair has further said that the satellite integration was almost complete and ISRO would be starting the Thermovac test in about a week's time. As this test would take about 45-50 days, ISRO would announce the new launch date after that. After September the next launch window available based on appropriate alignment between planets is expected to be in October. When SciFSN spoke to ISRO personnel, they confirmed the same and further added that for some reason if the tests are not completed, the launch may be further shifted to 15 November 2008.

Need to Design and Market Better Cooking Stoves

¶5. (U) In anticipation of an upcoming HHS/CDC Joint Indo-U.S. Workshop on Indoor Air Pollution next month in Chandigarh, SciOff met with staff from two local NGOs to discuss their efforts to reduce people's exposure to smoke from household heating and cooking. The NGO Development Alternatives said it feels more R&D is needed because only a "quantum leap" in stove technology will attract people to a cleaner-burning product. Winrock International India said that GOI has shied away from improved cookstove distribution programs because they are an "administrative nightmare" with no government champion. Both organizations agreed that future programs must use more social marketing to help people understand the negative health effects of indoor air pollution. Details from the meetings will inform a pending cable on indoor air pollution in India.

¶6. (U) The first of the series of collaborations between HHS/FDA and the Ministry of Health (MOH)/Drug Controller General of India (DCGI) is due to kick start during the first week of September in New Delhi. HHS/FDA in collaboration with the MOH/DCGI will hold the first of a three-part series of 'train-the-trainer' workshops to develop knowledge and skills in inspecting clinical trial sites, implementing a Good Clinical Practices (GCP) inspection program, and training future GCP inspectors. HHS/FDA subject experts will provide the training to GOI officials including DCGI officials and State Drug Controllers. The workshop will include a visit to an industry-run clinical research site.

¶7. (SBU) The DCGI suggested that he will invite the Health Minister to formally inaugurate the FDA Bhavan (Building) one-day prior to the GCP September workshop. SciOff feels this will be a good photo-op and media blitz for the USFDA to kick-start its collaborations on regulatory affairs with India and will seek to make this a joint Mission PA event with DCGI's office with high-level Mission participation.

¶8. (SBU) India presently is dragging its feet on making a policy

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decision and the approval is pending with the Ministry of Health as to who the partner countries will be for collaborations in the area of regulation of drugs and pharmaceuticals, medical devices, clinical trials, biologics. To ascertain the status of this decision, Mission Health Attach and FSN met with the DCGI Dr. Surinder Singh. The DCGI upfront spoke of the pending policy decision on India regulatory collaborations with Health Secretary Naresh Dayal. Singh requested the assistance of Health Attach, with his ability and rapport with the Health Minister, to direct the policy decision in favor of the USFDA, and not towards Health Canada. DCGI stated that Health Canada was not of the same caliber as the USFDA. Health Attach has met Minister's Personal Secretary and found out that Minister is aware of Secretary Dayal's views and that the Minister also wants close interactions with FDA. [Comment: It seems that collaborations on regulations of biologics will be to Health Canada and the other areas such as regulation of medical devices, drugs and pharmaceuticals, clinical trials with the USFDA. According to the DCGI, Secretary Dayal in spite of his personal opinions on who to collaborate with in the various aspects of regulatory affairs will in all likelihood give in to the wishes of his Minister. End Comment.]

¶9. (SBU) The DCGI also expressed his Office's inability to properly function due to a shortage of technically-qualified inspectors. There are just 12 inspectors with a mandate to increase to 50 for engaging with a potential USD 1 billion drug industry and a USD 2 billion medical devices market.

¶10. (SBU) In the same meeting, the DCGI provided an update of the status of the pending legislation on the Central Drug Authority or CDA. The DCGI said that a new technicality has arisen in the bureaucracy of the CDA, originally spoken of in the media and other circles as the Central Drug Authority. A re-look at the Mashelkar Committee Report observed that it recommended the creation of a 'Central Drug Administration' and not a 'Central Drug Authority' as widely believed. The DCGI is in fact relieved it will be an 'Administration' and not an 'Authority' for multiple reasons. The first is that an 'Administration' will function as a Department under the MOH and the DCGI will report directly to the Health Secretary. Secondly, this Department will have a separate budget allocation. Thirdly, the likelihood of a Board constituting 5 'retirees' to whom the DCGI will have to function in consensus with will not be required. In the 'Authority' model, this would have in the DCGI's opinion retarded fast-track growth of his organization with 'retirees' putting into force their own personal agendas with industry. The DCGI is looking forward to directly reporting to the Secretary Health in the new proposed system instead of the present reporting to the Directorate General of Health Services.

HHS Office supports Mission for DAS Vineyard's India Visit

¶11. (SBU) HHS India Office supports Mission for the upcoming visit of Ms. Holly Vineyard, the Deputy Assistant Secretary (DAS) for Africa, the Middle East, and South Asia at the U.S. Department of Commerce International Trade Administration. She will be visiting New Delhi from August 25-28, 2008 as the chief interlocutor of the U.S. - India High Technology Cooperation Group (HTCG). Ms. Vineyard is leading a delegation of U.S. regulatory officials and representatives from the private sector including senior officials from pharmaceutical companies.

HHS India Office Support to Other Upcoming Events

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¶12. (U) The HHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID) CTU site visit was held at B.J. Medical College in Pune on August 6, 2008. Acting Director General of the Indian Council of Medical Research Dr. S.K. Bhattacharya and Health Attach attended the site visit.

¶13. (U) HHS/NIH/NIAID and India's Ministry of Defense are co-hosting the Medical Countermeasures for Radiation Injury workshop from August 17-20 in New Delhi to explore mutual research interests related to the detection and treatment of injuries associated with intentional or accidental radiation exposure. Approximately 100 participants are expected including Indian Defense Ministry leadership, senior officials from the National Disaster Management Authority and the Defense Research and Development Organization. The U.S. delegation will include NIAID and DoD scientists, Biomedical Advanced Research and Development Authority (BARDA), leadership and researchers from U.S. academic institutions.

HHS/CDC Lab Quality Assessment of National Reference Laboratories

¶14. (SBU) At the request of India's National AIDS Control Organization (NACO), HHS/CDC in collaboration with the World Health Organization (WHO) and other partners, led an independent assessment of the 13 National Reference Laboratories (NRLs) across India to provide an unbiased view of the current quality of HIV testing and to provide recommendations linked to observed deficits for further strengthening these laboratories. The assessment report has been submitted to the GOI who has initiated implementation of several of the report recommendations. The assessment focused on 8 quality systems elements across all HIV testing. Gaps were found in: 1) documentation and record; 2) organization and personnel; 3) equipment; 4) procurement and inventory; 5) information and management; 6) process control, external and internal quality assurance and customer service; 7) occurrence and incidence management process; and 8) facility and safety. HHS/CDC Team has made recommendations on each of the above areas and NACO has started implementing recommendations. Over the next year most of these NRLs will be strengthened, re-assessed and then go through an NABL accreditation (international standards are followed for this level of accreditation). NACO has agreed to provide funds to each lab for NABL accreditation. For further information on this please contact New Delhi CDC Country Representative Dr. Rubina Imtiaz (email Imtiazr@in.cdc.gov).

HIV/AIDS Related News

¶15. (U) A study conducted by the WHO for NACO estimates that nearly 10,000 HIV infected people are being treated by private physicians in India. These physicians are following irrational drug combinations and faulty regimens making the patients resistant to the first line antiretroviral (ART) drugs faster than usual. Around 17 percent of the drugs being recommended by private practitioners are single ingredient drugs while the standard international protocol to treat HIV/AIDS is with a triple drug combination therapy. The study, presented at the 17th International AIDS Conference in Mexico City also observed that some Indian pharma companies are delivering the highly toxic ART drugs directly to

overcome patient's reluctance to visit pharmacies, in fear of stigma and discrimination.

¶16. (U) India's greatest challenge is in its fight against AIDS are gay men. An alarming increase in the number of gay men with NACO estimates of 2.5 million gays of which 100,000 are at a high risk of

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contracting HIV due to multi-partner and commercial sexual practices. According to NACO, gays are a very high risk community in India. At present, India has 800 targeted interventions of which 200 are for gays. India believes that 5% of all sexually active males in India have sex with other men, with Tamil Nadu, Andhra Pradesh and Orissa reporting the highest number of cases.

¶17. (U) Swiss drug maker F Hoffmann-La Roche Ltd may move the Madras High Court against patent infringement of its anti-infection drug Valcyte by Cipla Ltd., intensifying an ongoing legal battle between the two companies over patented drugs and their copycat versions. Cipla had launched a cheap generic version of valganciclovir (the active ingredient of Valcyte) in India under the brand name Valcept. Valcyte is widely prescribed for infections related to HIV/AIDS. If it is filed, the suit will be Roche's second in India related to patent infringement. In the first case, pending with the Delhi High Court, the company had sought an injunction on its cancer drug Tarceva, also by Cipla.

New FSSA CEO to take Charge

¶18. (U) India's Ministry of Health and Family Welfare (MOH) Food Safety and Standards Authority (FSSA) CEO Mr. G. Balachandran has taken a new position as Additional Secretary in the MOH. Mr Jatinder Pal Singh I.A.S. of the 1977 cadre is slated to take charge as FSSA CEO. Mr. Singh prior appointment was as Chief Secretary of Goa State.

West Bengal AI Update

¶19. (U) As of August 4, 2008, the Public Health Branch of the Directorate of Health Services, Government of West Bengal, has notified that there is no avian influenza (AI) reported in poultry from the Animal Resources Department. There is also no human case reported for AI. The Government of India also reports no cases of poultry of human Avian Influenza in the rest of India.

India Polio Update

¶20. (U) According to the World Health Organization (WHO), as of August 4, 2008, 15 new polio cases (P1=2 and P3=13) were reported for 2008. The total number of polio cases in 2008 stands at 346 (P1=10 and P3=336).

Suspected Hantavirus in India

¶21. (U) According to India press reports (Hindustan Times, August 5, 2008), one girl died and another was hospitalized with suspected Hantavirus pulmonary syndrome (HPS) caused by Hantavirus in India's State of Uttarakhand from Dehradun and Tehri areas. The State administration has sent blood samples from the hospitalized patient to the National Institute of Virology (NIV) in Pune and the National Institute of Communicable Diseases (NICD) in New Delhi for testing. All India Institute of Medical Sciences Professor of Medicine Dr. Randeep Guleria stated "This disease is very rare in India." Though reports are claiming the presence of the virus in India this needs to be confirmed by the NIV Pune. [Comment: If confirmed India's public health authorities will be concerned. However, Hantaviruses that cause HPS in the U.S. are only known to be transmitted by certain species of rodents. End Comment.]

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